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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/758,759	01/11/2001	Thomas J. Hosted	ID0983K	9474

24265 7590 05/14/2004

SCHERING-PLOUGH CORPORATION  
PATENT DEPARTMENT (K-6-1, 1990)  
2000 GALLOPING HILL ROAD  
KENILWORTH, NJ 07033-0530

EXAMINER
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VIVLEMORE, TRACY ANN

ART UNIT	PAPER NUMBER
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1635

DATE MAILED: 05/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

## Office Action Summary

Application No.

09/758,759

Applicant(s)

HOSTED ET AL.

Examiner

Tracy Vivlemore

Art Unit

1635

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-36 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application (PTO-152)
- ☐ Other: \_\_\_\_.

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-17, 23-35, drawn to polynucleotides encoding everninomicin biosynthetic pathway gene products, classified in class 536, subclass 23.1.
- II. Claims 18, 19, 36, drawn to isolated polypeptides, classified in class 530, subclass 350.
- III. Claims 20-22, drawn to a modified *Micromonospora carbonacea* wherein an everninomicin biosynthetic pathway gene is knocked out, classified in class 435, subclass 252.3.
- IV. Claims 20-22, drawn to drawn to a modified *Micromonospora carbonacea* wherein an everninomicin biosynthetic pathway gene is over-expressed, classified in class 435, subclass 252.3.

The inventions are distinct, each from the other because of the following reasons:

1. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polynucleotides which function to encode the proteins of the everninomicin biosynthetic pathway and polypeptides which function to perform specific actions of the everninomicin biosynthetic pathway.

Art Unit: 1635

2. Inventions I and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polynucleotides which function to encode the proteins of the everninomicin biosynthetic pathway and a modified microorganism which functions with a knocked-out everninomicin biosynthetic pathway gene.

3. Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polynucleotides which function to encode the proteins of the everninomicin biosynthetic pathway and a modified microorganism which functions to over-express an everninomicin biosynthetic pathway gene.

4. Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polypeptides which function to perform specific actions of the everninomicin biosynthetic pathway and a modified microorganism which functions with a knocked-out everninomicin biosynthetic pathway gene.

5. Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are drawn to polypeptides which function to perform specific actions of the everninomicin biosynthetic pathway and a modified microorganism which functions to over-express an everninomicin biosynthetic pathway gene.

6. Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions have different effects. In invention III, an everninomicin biosynthetic pathway gene is knocked-out, while in invention IV an everninomicin biosynthetic pathway gene is over-expressed.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

***Restriction to a single nucleotide sequence***

8. Pursuant to 35 U.S.C. 121 and 37 C.F.R. 1.141, the nucleotide sequences listed in claim 1-36 are subject to restriction. The Commissioner has partially waived the requirements of 37 C.F.R. 1.141 and will permit a reasonable number of such

nucleotide sequences to be claimed in a single application. Under this policy, up to 10 of independent and distinct nucleotide sequences will be examined in a single application. (see MPEP 803.04 and 2434)

Claims 2 and 26 claim multiple nucleic acid sequences encoding different amino acid sequences of the everninomicin biosynthetic pathway. Although the claimed nucleotide sequences each target the same biosynthetic pathway, they are considered to be unrelated since each nucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each of these sequences has a unique nucleotide sequence which encodes a separate amino acid sequence and each nucleotide sequence targets a different and specific region of the everninomicin biosynthetic pathway.

Claims 4, 5 and 27 specifically claim multiple nucleic acid sequences of genes in the everninomicin biosynthetic pathway. Although the claimed nucleotide sequences each target the same biosynthetic pathway, they are considered to be unrelated since each nucleotide sequence claimed is structurally and functionally independent and distinct for the following reasons: each of these sequences has a unique nucleotide sequence and each nucleotide sequence targets a different and specific region of the everninomicin biosynthetic pathway.

Claims 19 and 36 claim multiple isolated amino acid sequences. Although the claimed amino acid sequences each target the same biosynthetic pathway, they are considered to be unrelated since each amino acid sequence claimed is structurally and functionally independent and distinct for the following reasons: each of these

sequences has a unique amino acid sequence and targets a different and specific region of the everninomicin biosynthetic pathway.

Furthermore, a search of more than one (1) of the sequences claimed in the claims described above presents an undue burden on the Patent and Trademark Office due to the complex nature of the search and corresponding examination of more than one (1) of the claimed sequences. In view of the foregoing, one (1) sequence is considered to be a reasonable number of sequences for examination. Accordingly, applicants are required to elect one (1) sequence.

9. If group I is elected, applicant must further elect a single amino acid SEQ ID recited in claim 2 or 26 and state its corresponding nucleotide SEQ ID NO. (For example, SEQ IDS 3 and 2 are a proper pair, SEQ IDS 7 and 110 are not). If the chosen SEQ ID encodes a gene product of the type recited in claims 6-11, applicant must designate which claims read on the elected invention.

10. If group II is elected, applicant must further elect a single SEQ ID recited in claim 19 or claim 36 for examination.

11. If group III is elected, applicant must further elect a single SEQ ID recited in claim 2 for examination.

12. To be considered responsive to this requirement, applicant must choose a group and a single sequence to be examined.

13. A telephone call was made to Thomas Triolo on May 5, 2004 to request an oral election to the above restriction requirement, but did not result in an election being made.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tracy Vivlemore whose telephone number is 571-272-2914. The examiner can normally be reached on Mon-Fri 8:45-5:15.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on 571-272-0760. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Tracy Vivlemore

  
KAREN A. LACOURCIERE, PH.D  
PRIMARY EXAMINER



Application/Control Number: 09/758,759

Page 8

Art Unit: 1635

AU 1635

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